

# **EXECUTIVE SUMMARY**

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## **PURPOSE**

To assess State pharmacy boards' oversight of State patient counseling laws.

## **BACKGROUND**

### **MISMEDICATION AS A NATIONAL PROBLEM**

Adverse drug reactions associated with the misuse of prescription drugs are widespread. They reduce the quality of health care received by millions of people. They also add as much as \$100 billion a year to health care costs.

Pharmacists can help address this problem--by serving as a last line of defense to identify and correct prescription errors and by providing patients with oral and written information to improve their understanding and use of prescription drugs. This patient education role has been of longstanding interest to The Food and Drug Administration (FDA) and is central to a public-private prescription information program recently approved by the Secretary of the Department of Health and Human Services (HHS).

### **STATE PATIENT COUNSELING LAWS HAVE QUESTIONABLE EFFECTS**

In 1990, Congress required that pharmacists offer to counsel Medicaid beneficiaries who present prescriptions and that States establish counseling standards. Nearly all States responded by passing patient counseling laws that extend to all patients, not just Medicaid beneficiaries. They look to State pharmacy boards to oversee compliance with the laws.

Recent survey results suggest that the offer to counsel often is not extended. Worse yet, investigations conducted by "shoppers" pretending to be patients reveal that pharmacists often fail to warn patients about drug interactions that could be harmful or even fatal. Our inquiry, based primarily on a survey of State pharmacy boards, focuses on the performance of the boards in ensuring compliance with patient counseling laws.

## **FINDINGS**

*State pharmacy boards have played an active role in explaining and urging pharmacist compliance with State patient counseling laws.*

During the past year, 38 of 46 responding boards conducted educational efforts directed to pharmacists.

The boards have carried out three major types of educational activities. They include: (1) the distribution of newsletters, (2) the presentation of information at professional association meetings, and (3) the provision of information during inspection visits.

*However, the boards' enforcement of the counseling laws has been minimal.*

They have made little use of "shopping" visits, whereby board representatives pose as patients to assess compliance with counseling requirements. In the past year, only 17 of 46 responding boards made such visits. Generally, they were made only to pharmacies against which a complaint had been lodged.

They have relied on inspection visits as the major means of enforcement. Such visits are conducted with widely varying degrees of frequency. At best they offer limited opportunities for assessing the extent and adequacy of counseling.

They have taken few final, formal disciplinary actions involving violations of patient counseling laws. Of the 354 actions taken during the past year by 23 reporting boards, 208 (59 percent) were in just 3 States.

*The boards identified major obstacles to the successful implementation of patient counseling laws.*

**ECONOMICS OF PHARMACY PRACTICE.** About three-fourths of the boards noted as a major obstacle the limited reimbursement for counseling services; about one-half noted the lack of pharmacy owners' commitment to counseling. Workload pressures on pharmacists often too great to allow for routine counseling.

**LIMITED PATIENT DEMAND.** About 60 percent of the boards underscored the lack of patient knowledge about the patient counseling requirements. Patients often reluctant to spend the additional time counseling would require.

**LACK OF RESOURCES FOR ENFORCEMENT.** Cited by close to one-half of the boards as a major obstacle. Insufficient staff support, especially for labor intensive "shopping" investigations. Complaints about having responsibility for enforcing Federal Medicaid counseling requirements without additional funding.

## **RECOMMENDATIONS**

The HHS Secretary and the FDA are committed to a public-private prescription information program that by the year 2000 will result in at least 75 percent of the individuals receiving new prescriptions being given useful patient written information. The Health Care Financing Administration (HCFA) is committed to Federal-State efforts that will result in full adherence to Medicaid patient counseling requirements.

Pharmacy boards, through their oversight efforts, have a vital role in ensuring that progress is made in providing individuals with useful written and oral information. Our review indicates that there is much room for progress in State oversight efforts and that

major obstacles impede the integration of counseling into pharmacy practice. We offer two sets of recommendations intended to address this situation--one to FDA, the other to HCFA.

*The FDA should collaborate with State pharmacy boards to collect survey data on the usefulness of written information offered to patients receiving new prescriptions.*

Pharmacy boards, in concert with FDA, could conduct "shopping" efforts to a sample of pharmacies to determine the extent and type of information being offered to patients. A joint effort of this kind would help FDA carry out its responsibility to measure progress being made in offering "useful" written information to patients. At the same time, it would facilitate State board oversight of counseling law provisions governing the provision of both oral and written information.

*The HCFA should facilitate State efforts to enforce the Medicaid patient counseling mandate.*

Working in partnership with the States and the above-noted HHS agencies, HCFA could take the following initiatives:

**DEVELOP AND ASSESS STATE PROGRESS TOWARD A PATIENT COUNSELING PERFORMANCE OBJECTIVE.** This objective could resemble the year 2000 objective noted above. The States' annual drug utilization review reports could reflect progress made in meeting it.

**DEVELOP GUIDELINES ON STATE OVERSIGHT OF THE FEDERAL PATIENT COUNSELING MANDATE.** Such guidelines, incorporating best practices currently being carried out by the States, could help State boards in developing cost-effective enforcement approaches.

## **COMMENTS ON THE DRAFT REPORT**

Within the Department, we solicited and received comments on the draft report from FDA, HCFA, the Health Resources and Services Administration (HRSA), and the Assistant Secretary for Planning and Evaluation (ASPE). From external organizations, we requested and received comments from the National Association of Boards of Pharmacy, the Citizens' Advocacy Center, Public Citizen's Health Research Group, the American Pharmaceutical Association, the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the American Society of Health-System Pharmacists. We include the complete text of comments in appendix C. Below we summarize the major thrust of the comments on our recommendations and, in italics, offer our responses. We made a number of minor edits in the report in response to comments.

#### **FDA, HCFA, HRSA, AND ASPE COMMENTS**

The FDA, HCFA, and ASPE concurred with our recommendations. *In our draft report, we suggested that one initiative that HCFA could take in facilitating State efforts to enforce the Medicaid patient counseling mandate would be to "facilitate the convening of a national symposium on oral counseling by pharmacists." In this final report, we have eliminated that suggestion because pharmacy associations have decided to sponsor such a symposium in September 1997. We still suggest, however, that HCFA pay careful attention to the issues raised in the symposium and that it exert leadership in examining and even showcasing constructive ways of addressing the major obstacles to patient counseling that we identified in this report.*

The HRSA did not comment specifically on the recommendations, but it noted that the draft report made it appear that it was the responsibility of the State pharmacy boards to enforce the Federal Medicaid patient counseling requirement. *We modified the introductory text to clarify that States typically have relied upon the boards as the enforcement arm for both Federal and State counseling laws.*

#### **EXTERNAL ORGANIZATIONS' COMMENTS**

These comments serve as an important complement to our report. They add useful perspective, especially with respect to the obstacles to patient counseling. The associations tend to emphasize the need for Federal initiatives to address these obstacles (especially with respect to the economics of pharmacy practice) while more generally expressing their concern about any broadening of the Federal role. The consumer-based organizations call for stronger Federal action in ensuring that patients are adequately informed. *We are sensitive to the scope of the obstacles inhibiting oral counseling by pharmacists and to the primary role of State government in enforcing existing counseling laws. At the same time, we must reemphasize that our survey reveals that the enforcement of Federal and State oral counseling laws has been minimal. It is vital, we believe, for both levels of government to give greater attention to the implementation of these laws and to support "shopping" and other techniques toward that end.*